

Federal Taxation of the Drug Industry and Its Effects on New Drug Development

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Summary

A key issue in congressional debates over expanding consumer access to prescription drugs is the impact of proposed initiatives on the development of new medicines. Some of the initiatives entail significant changes in one or more of the federal policies affecting new drug development. One such policy is federal taxation of firms that invest in this development.

This report examines the impact of federal taxation on the incentive to invest in new drug development. More specifically, it looks at the provisions in current tax law that affect the performance of the drug industry, compares the industry's federal tax burden with that of other major industries, and assesses the effect of federal taxation on the incentive to invest in new drug development. This information may be useful to the 111th Congress as it considers the pros and cons of proposed changes in the U.S. health care system. The report will be updated as necessary.

An industry's federal tax burden refers to the effects of federal taxation on its return on investment through statutory provisions that define taxable income, make adjustments to this income, and establish tax rates and credits against tax liability. Economists generally measure an industry's federal tax burden as its average effective tax rate, which is the ratio of its federal tax liability after all credits (except the foreign tax credit) to its taxable income, expressed as a percentage. This measure has some limitations, such as the inability of average effective rates to capture the effects of tax provisions that accelerate the timing of deductions or delay the recognition of income.

A comparison of average effective federal tax rates for the drug industry and major U.S. industries indicates that the share of the drug industry's worldwide net income paid as federal taxes was similar to the average share for all industries from 2000 through 2006. This has not always been the case. For much of the 1990s, the drug industry's tax burden was significantly lower than the average tax burden for all industries. But starting in the late 1990s, the drug industry's federal tax burden began to rise as the U.S. possessions tax credit was phased out. Drug firms were major beneficiaries of this credit. They also appear to benefit substantially, if not disproportionately, from three tax preferences whose combined effect is not fully reflected in average tax rates: (1) the deferral of federal income tax on the retained earnings of foreign subsidiaries of U.S.-based corporations, (2) the expensing of research outlays, and (3) the expensing of advertising outlays.

Available evidence suggests that current federal tax law bolsters the incentive to invest in new drug development for some firms but not for others. The most powerful drivers of this investment seem to be the quest by certain drug firms for sustained competitive advantage and profit growth and the available technological opportunities for developing new, safe, and effective medicines. Still, all other things being equal, a substantial increase in the industry's tax burden might slow growth in this investment by raising the industry's cost of capital and reducing its cash flow.

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At times, it appears that a major segment of the drug industry cannot avoid being the center of controversy. Firms that develop, produce, and sell brand-name or patented drugs have been praised for their successes in developing safer or more effective versions of existing medicines and new medicines that advance the treatment of a variety of diseases.¹ Yet these same firms have been rebuked for selling the same drugs at higher prices in the United States than in many other developed countries; their attempts to minimize competition from cheaper generic drugs; their relatively high profitability; and spending as much or more on advertising and product promotion than research and development (R&D).²

Framing these contrasting sentiments is a continuing debate among lawmakers over the best way to improve access to medicines for Americans of all ages and income levels, without establishing costly new federal entitlement programs or undermining key incentives for new drug development.

An important issue in this debate is the likely impact of initiatives of this sort on the commercial development of new medicines. Some initiatives would entail significant changes in one or more of the federal policies affecting new drug development. The federal government plays a varied and far-reaching role in that process. This role encompasses a variety of laws and programs, including direct federal funding of drug-related research and development (R&D), federal regulation of the safety and efficacy of new medicines and the use and promotion of approved medicines, federal patent protection for prescription drugs, federal support of biomedical research and education in universities, federal financing of drug purchases through Medicaid and Medicare, and federal tax subsidies for research and the purchase of health insurance and medicines.

This report examines one of the federal policies influencing the domestic climate for new drug development: federal taxation of firms that develop, produce, and sell drugs as a main line of business. As will be seen, the federal tax code affects the incentive to invest in new drug development in several ways. The net result of these interactions forms the core of the report.

More specifically, the report analyses the drug industry's federal tax burden from 1995 to 2006, the most recent year for which federal corporate tax return data are available. This burden refers to the federal income taxes paid by drugmakers as a percentage of their taxable income; tax returns with and without net income are used to compute the industry's federal tax burden. Depending on its size, this burden has the potential to constrain the incentives for business investment in new drug development. The report begins with an examination of the distinguishing traits of the drug industry, then identifies the tax provisions that have the biggest impact on the industry's return on investment, and concludes with an assessment of the effects of federal taxation of the industry on the incentives to invest in new drug development.

¹ In 2007, companies that were members of the Pharmaceutical Research and Manufacturers of America, the principal U.S. trade association for the pharmaceutical industry, spent an estimated \$35.4 billion on domestic pharmaceutical research and development (R&D), up from \$21.4 billion in 2000. (See Pharmaceutical Research and Manufacturers of America, *Pharmaceutical Industry Profile 2008* (Washington: 2008), p. 52, available at <http://www.phrma.org>.) The number of new molecular entities and new biologics approved by the U.S. Food and Drug Administration dropped from 36 in 2004 to 18 in 2007.

² According to the most recent data for the Fortune 500 companies, the ratio of after-tax income to revenues for the pharmaceutical industry in 2007 was 15.8%, compared to a median ratio for all Fortune 500 companies of 6.5%. Total promotional spending by the pharmaceutical industry totaled an estimated \$10.4 billion in 2007, down from \$11.9 billion in 2004. (See the Henry J. Kaiser Family Foundation, *Prescription Drug Trends* (Washington: Sept. 2008), p. 2, available at <http://www.kff.org>.)

As discussed in this report, the drug industry encompasses a varied collection of corporations, all of whom derive the largest share of their income from one or more of the following commercial activities: (1) manufacturing biological and medicinal products; (2) processing botanical drugs and herbs; (3) isolating active medicinal ingredients from botanical drugs and herbs; and (4) producing pharmaceutical products intended for internal and external use in such forms as tablets, capsules, powders, ointments, and solutions.³ This group of firms includes both large, traditional pharmaceutical firms that tend to concentrate on developing small-molecule drugs from chemicals, makers of generic versions of such drugs, and small, fledgling biotechnology firms that focus on developing biologics, which are large-molecule drugs derived from living cells.

In the period examined here, the vast majority of drug firms had no net income, and thus no tax liability. But drug firms with net income accounted for most of the industry's assets and gross income.⁴ It is unclear from available business tax data if the drug firms with losses were primarily producers of pharmaceuticals or biologics.

Excluded from the group of drug firms discussed here are firms organized as non-corporate entities, such as partnerships and limited liability companies. It is not known how much these firms contribute to total income, assets, employment, or tax liability for the drug industry. But their shares are unlikely to be substantial, since the drug firms (e.g., GlaxoSmithKline, Merck, Pfizer, Lilly, Amgen) that account for most industry profits and taxes are all organized as corporations.

The information presented here may be of use to the 111th Congress as it weighs the advantages and disadvantages of proposals to modify how health care is financed and delivered in the United States.

Distinguishing Characteristics of the Drug Industry Relevant to Its Federal Tax Burden

Many industries have distinctive traits, which can be thought of as defining features tied to the goods and services they sell, the technologies used to produce them, and the main forces driving competitive success and long-term growth in employment and output. The drug industry is one of these industries. What arguably distinguishes firms that develop, produce, promote, and sell patented or branded drugs is their propensity to invest heavily in R&D and advertising, a focus on certain therapeutic categories to the exclusion of others, a strong reliance on patents to generate profits and bolster competitiveness, and an extensive network of foreign subsidiaries. As this report shows, several of these traits have important implications for the industry's federal tax burden.

Heavy Spending on R&D Relative to Sales

The drug industry is one of the most research-intensive of all U.S. industries. This means that it spends a large amount on R&D relative to its receipts. At the same time, drug firms receive little

³ This definition matches the definition of the pharmaceutical and medicine manufacturing industry (sector 32451) used in the North American Industry Classification System (NAICS). The Internal Revenue Service (IRS) uses this system to classify corporate tax returns by industry.

⁴ In 2006, for example, only 510 out of the 1,678 tax returns filed by corporations classified by the IRS in the drug industry reported net income or income subject to taxation. But the 510 firms with net income accounted for 86% of industry assets and 91% of industry receipts.

direct R&D funding from federal government agencies. According to estimates by the National Science Foundation, U.S. producers of drugs and medicines spent the equivalent of 12.7% of domestic net sales on domestic R&D in 2005; by contrast, the same ratio that year was 3.3% for all industries and 3.6% for manufacturing.⁵ U.S. producers of drugs and medicines spent \$34.8 billion of their own and other non-federal funds on domestic R&D in 2005, while federal spending on domestic drug R&D totaled only \$41 million.

Many drug firms invest heavily in R&D simply because it has long served as the industry's primary engine for growth in sales and profits. Those that become industry leaders achieve and sustain their stature by developing a steady stream of products that gain wide acceptance among doctors and their patients. Though discovering and developing new drugs often is a time-consuming, risky, and costly process,⁶ firms that succeed can earn sizable profits, at least until generic versions of the drugs or so-called me-too patented drugs enter the market.⁷ Because drug patents have a finite life, leading drug firms face continuing pressure to develop new and innovative drugs to lay a solid foundation for future growth. Those firms whose development efforts falter often end up struggling to survive in the face of stiff generic competition for their key drugs whose patent protection has expired. In recent years, some firms in this position have merged with larger, more successful firms in order to remain in business, while those that develop so-called blockbuster drugs prosper.⁸

Advances in the technology for finding promising new drug candidates over the past quarter century have greatly increased the number of drug compounds with significant therapeutic potential being discovered. Yet the entry of new breakthrough drugs into the market appears to have slowed considerably in the past 10 to 20 years. A 2002 study by the National Institute for Health Care Management Foundation found that 35% of the 1,035 new drug applications approved by the FDA from 1989 to 2000 were new molecular entities (NMEs), which the FDA defines as drugs containing novel active ingredients, and that about one-third of those NMEs (or 15% of new drug approvals) were deemed to offer significant therapeutic advantages over existing drugs.⁹ In addition, the number of NMEs approved by the FDA has decreased steadily since reaching a peak of 56 in 1996: a total of 17 NMEs were approved in 2007.

Substantial Investment in Advertising and Product Promotion

Most major drug firms also spend large sums on promoting the use of their branded products directly to physicians and consumers. Firms that develop new innovative medicines seem

⁵ National Science Foundation, Division of Science Resources Statistics, *InfoBrief: Expenditures for U.S. Industrial R&D Continue to Increase in 2005; R&D Performance Geographically Concentrated*, NSF 07-335 (Arlington, VA: Sept. 2007) tables 2 and 3, pp. 3-4.

⁶ According to research findings summarized by PhRMA, the period from the synthesis of a new compound to its approval by the U.S. Food and Drug Administration (FDA) can last 10 to 15 years; only one out of every 5,000 compounds synthesized in a laboratory ends up gaining FDA approval; the cost of developing a new drug (including the cost of failures) rose from \$175 million in 1975 to \$1.3 billion in 2006 for large pharmaceutical firms; and only two out of 10 newly approved drugs earn enough revenues to cover their R&D cost. See Pharmaceutical Research and Manufacturers of America, *Profile 2008: Pharmaceutical Industry* (Washington: 2008), p. 6.

⁷ When a drug loses its patent protection, several generic drug makers typically enter the market at once, charging prices that are as much as 80% below the price for the original patented drug. This price competition usually causes the market share of the seller of that drug to drop sharply in a relatively short time.

⁸ A blockbuster drug is commonly thought of as a drug whose annual worldwide sales equal or exceed \$1 billion. See Herman Safitlas, *Industry Surveys, Healthcare: Pharmaceuticals* (Standard & Poor's, Nov. 27, 2008), p. 22.

⁹ National Institute for Health Care Management Foundation, *Changing Patterns of Pharmaceutical Innovation* (Washington: May 2002), p. 3, available at <http://www.nihcm.or/research>.

especially inclined to invest heavily in advertising. Early in a new drug's commercial life cycle, advertising and promotion typically are aimed at capturing a major share of the market as quickly as possible. But later in the cycle, the main thrust of these efforts often shifts to fending off or thwarting competition from generic drugs or me-too drugs.

According to one source, promotional spending by drug firms totaled \$10.4 billion in 2007, down from \$12.0 billion in 2006, but up from \$4.3 billion in 1996. Of the amount spent in 2007, \$3.7 billion went into direct advertising to consumers, and \$6.7 billion was directed at physicians and other health care providers.¹⁰

The high priority given to informing doctors and encouraging what seems to be a form of brand loyalty among them reflects a fundamental feature of the market for prescription drugs that is absent from the markets for many other consumer goods and services. In deciding which drugs to use in treating an illness, consumers defer to the judgment and consent of third parties—namely, doctors and insurance companies.

Fragmented Competitive Structure

Another distinguishing trait of the drug industry is its fragmented competitive structure. This fragmentation has two critical aspects. One concerns the markets for brand-name drugs themselves; the other is related to what might be described as the technological focus or orientation of drug firms.

No single firm or small cluster of firms dominates the domestic market for branded drugs. According to U.S. Census Bureau, in 2002, the most recent year for which figures are available, the four largest producers contributed 34% of the value of domestic shipments of medicines; the eight largest, 49%; and the 20 largest, 70%.¹¹ The absence of a dominant seller is partly due to the multitude of therapeutic categories and the high cost of carving out a position of dominance in any particular category. Some drug formularies, which are lists of approved drugs that are covered under specific insurance plans, encompass as many as 16 therapeutic categories and over 100 sub-categories. Drugs classified in one sub-category generally cannot be substituted for drugs in another sub-category. For this reason, the economist F. M. Scherer once described the drug industry as a “collection of differentiated oligopolies.”¹²

Nonetheless, some firms are able to establish at least a temporary supremacy in certain segments of the market for prescription drugs. Such dominance is most likely to arise when a firm brings a new innovative drug to the market. For example, Wyeth has dominated the market for female hormone replacement therapy, while Pfizer has captured a substantial lead in the market for cholesterol-reducing medications. Some firms create what amount to new markets with their drug innovations, as Pfizer did with its launch of Viagra for the treatment of erectile dysfunction, and Merck did with its development of Proscar for the treatment of enlarged prostate glands.¹³

The drug industry can also be divided into three subgroups that differ primarily in their approach to new drug development. Those subgroups are pharmaceutical firms, biotechnology firms, and generic drug firms. Though mergers and strategic alliances involving firms from all subgroups have blurred the boundaries among the three subgroups in recent years, it still remains the case

¹⁰ Kaiser Family Foundation, *Prescription Drug Trends* (Washington: Sept. 2008), pp. 2-3, available at <http://www.kff.org>.

¹¹ U.S. Census Bureau, *2002 Economic Census: Concentration Ratios in Manufacturing* (Washington: May 2006), Table 2, p. 27.

¹² F. M. Scherer, *Industry Structure, Strategy, and Public Policy* (New York: HarperCollins, 1996), p. 337.

¹³ Standard & Poor's Industry Surveys, *Healthcare: Pharmaceuticals*, p. 33.

that pharmaceutical firms tend to focus on developing small-molecule drugs from chemicals; biotechnology firms tend to focus on developing biologics, which are large-molecule drugs derived from living cells; and generic drug firms tend to focus on making low-cost copies of branded drugs that have lost their patent protection. While comprehensive data on profits for firms in each subgroup are hard to find, there is little doubt that the average pharmaceutical firm is larger in assets, sales, and employment, and more profitable than the average biotech or generic drug firm. Pharmaceutical firms compete against biotech and generic drug firms in many therapeutic categories. But the scope of competition between the pharmaceutical and biotech subgroups has narrowed in recent years, as pharmaceutical firms have invested tens of billions of dollars in acquiring biotech firms.¹⁴

Strong Reliance on Patent Protection under Regulatory Oversight by the Food and Drug Administration

The central role played by technological innovation in the growth and transformation of the drug industry over time points to another key distinguishing trait of the industry: a heavy reliance by leading firms on patents for drugs that have gained regulatory approval to generate relatively high rates of return on investment and bolster or sustain their dominance in segments of the market where they compete.

Patents grant to their owners a temporary legal monopoly over the commercial uses of an invention. In the United States and most other advanced industrialized nations, the life of a patent has been 20 years from the date of application since June 8, 1995. A patent holder may license other firms to exploit the invention in exchange for royalties, which can be thought of as compensation for relinquishing exclusive control over the commercial applications of a new technology.

Drug firms claim patents for the design of drug compounds, their formulation as drug therapies, their uses in treating diseases, and their methods of manufacture.¹⁵ Under the Drug Price Competition and Patent Term Restoration Act of 1984, drug companies may obtain an extension of the life of their patents of as much as five years to compensate for time lost during clinical testing.¹⁶

Patents serve as an important competitive weapon for leading drug firms. Their usefulness in the quest for profits and growth is inextricably bound up with the lengthy, costly, and stringent approval process that all promising new drug candidates must undergo before they can be sold in the United States. The Food and Drug Administration (FDA) regulates the introduction of new drugs. It requires that new drugs pass through three phases of clinical testing on humans. Phase I is intended to test the safety of a new drug. Phase II begins to test the efficacy of the drug, as it continues to examine its safety at higher doses. In the third and final phase, the drug is subjected to more complex and rigorous tests for the purpose of ascertaining its safety, efficacy, and optimal dosages using relatively large groups of ill patients. Once the FDA confers its stamp of approval, everyone in the industry knows what the innovating drug company knows: that the drug provides the desired therapy. In the absence of patent protection, imitators could easily develop identical

¹⁴ Ibid., p. 13.

¹⁵ U.S. Congress, Office of Technology Assessment, *Pharmaceutical R&D: Costs, Risks, and Rewards* (Washington: GPO, Feb. 1993), pp. 290-293.

¹⁶ For more details on the provision in the act allowing for patent-term extensions, see CRS Report RL30756, *Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984 ("The Hatch-Waxman Act")*, by Wendy H. Schacht and John R. Thomas.

substitutes at a fraction of the cost incurred by the innovator. But by obtaining a patent for the molecular design of the drug, the innovator can effectively block entry by substitutes for a number of years, as slight variations in the design must undergo the full testing and approval process.

For this reason, it is not surprising that drug industry executives tend to view patents as a highly effective mechanism for appropriating the returns to investment in R&D. According to the results of a survey of 650 R&D managers from 130 industries conducted by Richard Levin in the mid-1970s, R&D managers in the pharmaceutical industry gave product patents a higher rating as a means of protecting the competitive advantages from technological innovation than did the R&D managers in any other industry.¹⁷ More recently, in an analysis of the results of a 1994 survey of R&D managers at U.S. manufacturing firms with a minimum of \$5 million in sales or with business units with at least 20 employees, Wesley Cohen, Richard Nelson, and John Walsh found that the drug industry had the highest mean percentage (50.2%) of product innovations for which patents were deemed an effective mechanism for capturing the returns to those innovations; the average mean percentage for patents for all manufacturing industries was 34.8%.¹⁸

The industry's aggressive use of patents for products that have gained regulatory approval may explain why drug firms have long been among the most profitable of all firms. From 1960 to 1991, the reported rate of return on stockholders' equity for the pharmaceutical firms included in the annual ranking of the top 500 industrial corporations by *Fortune* magazine averaged 18.4%, compared to 11.9% for all firms;¹⁹ as recently as 2001, pharmaceuticals ranked first in return on shareholders' equity (33.2%) among the 48 industries represented in the *Fortune* 500; in 2007, the industry ranked 12th (20.3%) out of 51 industries.²⁰ One indication that patents are critical to the profitability of drug firms lies in the difference in selling prices between branded drugs and their generic counterparts. Patented medicines often command much higher prices than their generic counterparts, which enter the market only after the patents expire.²¹

Extensive Foreign Operations

No account of the distinctive traits of the U.S. drug industry with a bearing on its federal tax treatment would be complete if it failed to mention the industry's extensive operations in U.S. possessions and foreign countries. For many U.S.-based drug firms, these operations have had a significant impact upon their revenue streams, competitive postures, and federal tax burdens. Most major U.S. drug firms own foreign subsidiaries that manufacture and sell drugs and conduct R&D; many of these subsidiaries are located in Europe and Japan, the two largest regional markets (measured in U.S. dollars) for patented medicines after the United States.²² Like U.S.

¹⁷ F. M. Scherer, *Industry Structure, Strategy, and Public Policy* (New York: Harper-Collins, 1996), p. 361.

¹⁸ Wesley M. Cohen, Richard R. Nelson, and John P. Walsh, *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or not)*, working paper 7552 (Cambridge, MA: National Bureau of Economic Research, Feb. 2000), table 1, p. 32.

¹⁹ *Ibid.*, p. 342.

²⁰ Available at <http://money.cnn.com/magazines/fortune/fortune500>.

²¹ Once a prescription drug's patent expires, one or more generic versions, which are chemical copies of the patented drug, usually become immediately available at lower prices. The price of a new generic drug is typically 25% to 50% lower than that of its branded counterpart.

²² According to IMS Health Inc., drug sales in the United States totaled \$207.4 billion in the 12 months ending in July 2008, while Japan recorded drug sales of \$64.4 billion and combined sales in Germany, France, Italy, Spain, and the United Kingdom came to \$32.3 billion. See Standard & Poor's *Healthcare: Pharmaceuticals* (New York: Nov. 27, 2008), p. 10.

automobile producers, major pharmaceutical firms recognized in the 1960s that if they were to have success in foreign markets, they needed to establish a manufacturing and research presence in those markets.²³

There are several ways to illuminate the large foreign presence of the drug industry. Perhaps the most comprehensive source of data on foreign direct investment abroad by U.S. firms is the U.S. Department of Commerce. According to Commerce data, in 2005, a total of 46 U.S.-based drug firms with domestic assets valued at \$447 billion had established a total of 421 majority-owned foreign affiliates with assets valued at \$181 billion.²⁴ Most of these firms should be regarded as pharmaceutical firms. Sales by the foreign affiliates that year totaled \$126 billion, and they employed 207,900 workers.

A second but more limited source of information on the foreign operations of U.S. drug firms is the Pharmaceutical Research and Manufacturers of America (PhRMA), the primary trade association for the domestic drug industry. Most member companies should be regarded as pharmaceutical firms. In 2007, domestic sales by PhRMA member companies amounted to an estimated \$190 billion, while foreign sales by U.S.-based PhRMA member companies and the U.S. affiliates of foreign-based PhRMA member companies totaled an estimated \$82 billion, or 43% of domestic sales.²⁵ In the same year, PhRMA member companies spent an estimated \$35 billion on domestic R&D, while foreign R&D spending by U.S.-based PhRMA member companies and the U.S. affiliates of foreign-based PhRMA member companies totaled an estimated \$9 billion, or 26% of domestic R&D spending.²⁶

Although the importance of foreign markets varies from company to company, it appears that the U.S. drug industry may derive as much as 40% of its revenue from foreign sales.²⁷ The industry's foreign operations may account for an even higher portion of its overall profits. In 2003, six of the largest U.S.-based pharmaceutical firms received over 65% of their combined profits from foreign operations, up from about 38% in 1994.²⁸

Federal Income Taxes Paid by the Drug Industry Between 1990 and 2006

Federal income taxes paid from 1990 to 2006 by corporations that derive the largest share of their income from the manufacture and sale of drugs are shown in **Table 1**. The figures in the table are taken from tax returns filed by corporations with and without net income and include any corporate alternative minimum taxes owed by drug firms.

In collecting and publishing corporate tax data by industry, the IRS defines the drug industry in the same manner as the North American Industry Classification System. According to that definition, the industry consists of firms that derive the largest share of their revenue from one or more of the following sources: manufacturing biological and medicinal products; processing

²³ Scherer, *Industry Structure, Strategy, and Public Policy*, p. 342.

²⁴ The data can be accessed at <http://www.bea.gov/bea/di/home/directinv>.

²⁵ Pharmaceutical Research and Manufacturers of America, *Pharmaceutical Industry Profile 2008* (Washington: PhRMA, 2008), p. 58, available at <http://www.phrma.org>.

²⁶ *Ibid.*, p. 52.

²⁷ Standard & Poor's, *Healthcare: Pharmaceuticals*, p. 31.

²⁸ The firms were Pfizer, Johnson & Johnson, Merck, Bristol-Myers Squibb, Abbott Laboratories, and Schering Plough. See John A. Almond and Martin A. Sullivan, "Drug Firms Park Increasing Share of Profits in Low-Tax Countries," *Tax Notes*, Sept. 20, 2004, p. 1,336.

botanical drugs and herbs; isolating active medicinal ingredients from botanical drugs and herbs; and manufacturing pharmaceutical products for internal and external use in forms such as tablets, capsules, vials, powders, and solutions.

The industry's taxable income shown in **Table 1** combines domestic income earned by U.S.-based corporations and U.S. affiliates of foreign-based firms and a portion of the income earned by foreign branches and subsidiaries of U.S.-based corporations.

Such a mix is appropriate because the United States, unlike many other developed countries, taxes business income on the basis of residence, not according to territorial source. Consequently, corporations chartered in the United States owe taxes to the federal government on their worldwide income. U.S.-based firms also pay income taxes to foreign governments on much of the income earned by their foreign affiliates. To avoid double taxation of this income, U.S. tax law permits U.S.-based firms to claim a credit for foreign income tax payments that cannot exceed their U.S. tax liability on the foreign-source income. In addition, U.S. affiliates of corporations chartered in other countries are required to pay federal income taxes on any income they earn in the United States. Federal tax law permits U.S.-based firms to defer the payment of federal income taxes on profits earned by their foreign subsidiaries until those profits have been repatriated to the U.S. parent.

Table 1. Federal Income Tax Liability for the Drug Industry, 1990 to 2006

(millions of dollars)

Year	Taxable Income	Federal Income Tax Before Credits	Tax Credits Claimed (Except the Foreign Tax Credit)	Income Tax After Credits (Except the Foreign Tax Credit)	Average Effective Tax Rate (%) ^a
1990	15,934	5,482	1,825	3,657	22.9
1991	17,452	6,026	2,070	3,956	22.7
1992	19,920	6,920	2,238	4,682	23.5
1993	19,997	7,092	2,441	4,651	23.2
1994	24,837	8,752	2,479	6,273	25.2
1995	23,963	8,502	1,880	6,622	27.6
1996	24,810	8,816	1,948	6,868	27.7
1997	27,627	9,729	1,983	7,746	28.0
1998	29,218	10,240	2,204	8,216	28.1
1999	30,912	10,851	1,138	9,713	31.4
2000	31,102	10,918	1,027	9,890	31.8
2001	32,958	11,435	1,060	10,375	31.5
2002	31,185	10,975	1,193	9,783	31.4
2003	40,186	14,112	2,010	12,102	30.1
2004	38,078	13,354	1,414	11,940	31.3
2005	60,117	21,080	1,563	19,517	32.5
2006	53,852	18,852	1,339	17,513	32.5

Source: U.S. Internal Revenue Service, Statistics of Income Division (SOI), *Corporation Source Book*, 1990 to 2006; covers corporate tax returns only, with and without net income; available at <http://www.irs.ustreas.gov/taxstats>.

- a. Income tax after credits (except the foreign tax credit) divided by taxable income and multiplied by 100.

It is clear from the figures in the table that the industry benefitted from existing business tax credits (excluding the foreign tax credit): from 1990 to 2006, its average tax liability after credits was 86% of its average tax liability before credits. (The reason for excluding the foreign tax credit from these calculations is explained below.) At the same time, it is clear that the combined value of these credits trended downward from 1990 to 2000 and then reversed course. The primary force behind this decline was a phase-out of the possessions tax credit that commenced in late 1997 and stretched through the end of 2005.

In addition, the relatively high levels of taxable income in 2005 and 2006 were due to the billions of dollars in foreign earnings drug firms repatriated from overseas subsidiaries under the temporary repatriation tax holiday established by the American Jobs Creation Act of 2004 (see pp. 19-20).

The main tax credits claimed by the drug industry are shown in **Table 2**. Their impact on the industry's federal tax burden is discussed below.

Foreign Tax Credit

Unlike the other tax credits shown in the table, the foreign tax credit confers no benefit on a firm that claims it. Section 901 of the Internal Revenue Code (IRC) permits a corporation chartered in the United States and paying income and related taxes to a foreign government through a foreign subsidiary to claim a limited credit for those taxes in the tax year when the foreign earnings are repatriated as dividends. This statutory provision is intended to avoid the double taxation of income earned by foreign branches or subsidiaries of U.S.-based corporations and repatriated to the U.S. parents. As a result, the foreign tax credit should be added to a firm's tax liability in measuring its federal tax burden. The credit may not exceed the federal income tax owed on repatriated foreign-source income and may not offset any federal tax owed on domestic-source income. In addition, the U.S. Treasury does not refund foreign income taxes paid in excess of the federal tax liability for repatriated foreign-source income. For foreign tax credits earned after October 22, 2004, any such excess may be carried back one year and then carried forward up to 10 years, subject to the same limitations.

Possessions and Puerto Rican Economic Activity Tax Credit

The drug industry was a major beneficiary of what was known until 1996 as the possessions tax credit under IRC Section 936. Under the Small Business Job Creation Act of 1996, the credit was revised and reborn as the Puerto Rican Economic Activity Credit (PREAC) under IRC Section 30A; it expired on December 31, 2005. In 2005, the industry was able to reduce its federal income tax liability by more than 2% by using the credit; drug firms accounted for 53% of the total amount of the credit claimed by all industries.

When the PREAC was available from 1997 to 2005, corporations chartered in the United States could exclude from federal taxation as much as 40% of their income from business operations in Puerto Rico, the U.S. Virgin Islands, and other U.S. territorial possessions. To take advantage of the exclusion, a firm had to derive 80% of its overall gross income from business operations in one or more of these possessions, and 75% from the active conduct of a business there.

The PREAC itself was equal to a firm's tax liability on possession-source income, subject to one of two alternative caps enacted in 1993. Under one cap—known as the “economic-activity limitation”—the credit was restricted to certain wage and depreciation costs; under the second cap—known as the “percentage limitation”—the credit was limited to 40% of the credit a firm

could have claimed under rules that applied before 1993. Under a provision of the Small Business Job Protection Act of 1996, the credit was modified to phase out by the end of 2005 for firms claiming it in 1996 and was repealed immediately for all other firms.²⁹ The act also set forth separate phase-out rules for firms subject to the percentage limitation and those subject to the economic-activity limitation.

There is some evidence the drug industry responded to the possessions tax credit by establishing a substantial manufacturing presence in Puerto Rico. According to a 1992 report by the then General Accounting Office, a total of 26 drug firms owned manufacturing operations there in 1990. The firms realized an estimated tax savings of \$10.1 billion that year from those operations, which produced 17 of the 21 most commonly prescribed drugs in the United States in the early 1990s.³⁰

Table 2. Main Federal Tax Credits Claimed by the Drug Industry from 1990 to 2006

(millions of dollars, unless otherwise noted)

Year	Foreign Tax Credit	Possessions Tax Credit	Prior-Year Alternative Minimum Tax Credit	General Business Tax Credit ^a		
				Orphan Drug Tax Credit ^b	Research Tax Credit	Total
1990	1,205	1,666	2	15	NA	142
1991	1,367	1,883	20	18	235	150
1992	1,613	2,033	7	17	264	180
1993	1,886	2,150	63	19	306	208
1994	1,960	2,116	73	19	307	271
1995	2,633	1,611	55	0b	164	214
1996	2,628	1,651	78	24	252	219
1997	2,204	1,591	63	52	552	329
1998	2,677	1,459	50	50	630	514
1999	2,938	866	50	66	714	222
2000	2,414	689	26	79	802	312
2001	2,280	621	23	70	806	416
2002	3,234	611	5	47	778	576
2003	4,842	594	5	89	736	1,411
2004	3,455	585	72	109	758	757
2005	6,655	466	129	142	915	968
2006	2,327	432	8	159	902	885

Source: U.S. Internal Revenue Service, SOI, *Corporation Source Book*, 1990 to 2006; covers tax returns only, with and without net income; available at <http://www.irs.ustreas.gov/taxstats>, and unpublished data obtained from SOI.

²⁹ For further details on the design of the credit and congressional proposals to extend it, see CRS Report RS20695, *The Puerto Rican Economic Activity Tax Credit: Current Proposals and Scheduled Phaseout*, by David L. Brumbaugh.

³⁰ U.S. General Accounting Office, *Pharmaceutical Industry: Tax Benefits of Operating in Puerto Rico*, GAO report GGD-92-72BR (Washington: May 1992), pp. 4-7.

- a. Under IRC Section 38, the general business credit is a limited, non-refundable credit against income tax that is claimed after all other non-refundable credits, except for the credit for the alternative minimum tax. The general business credit is the sum of the rehabilitation credit, the energy credit, the reforestation credit, the work opportunity credit, the welfare-to-work credit, the alcohol fuels credit, the research credit, the low-income housing credit, the enhanced oil recovery credit, the disabled access credit, the renewable resources electricity production credit, the empowerment zone employment credit, the Indian employment credit, the employer Social Security tip credit, the orphan drug credit, the new markets credit, small employer pension plan start-up costs credit, and the employer-provided child care credit.

There is a limit on the general business credit that a corporate taxpayer may claim in a given tax year: it may not exceed its tax liability less the greater of (a) the tentative alternative minimum tax or (b) 25% of regular tax liability above \$25,000. If the general business credit claimed in the current year exceeds this limitation, the excess or unused credit may be carried back one year or forward 20 years. With the exception of 1995, the combined value of the orphan drug tax credit and research tax credit claimed by the pharmaceutical industry exceeded the total general business credit it was permitted to claim by substantial margins. The reason lies in this limitation.

- b. The orphan drug tax credit was suspended from January 1, 1995 to June 30, 1996. Under the Small Business Job Protection Act of 1996 (P.L. 104-188), the credit was reinstated from July 1, 1996 to May 31, 1997 and made part of the general business credit. The credit has never been reinstated for the period from January 1, 1995 to June 30, 1996.

Prior-Year Minimum Tax Credit

Corporations over a certain size, like individuals, are subject to two parallel income tax systems: the regular income tax and the alternative minimum tax (AMT).³¹ Each tax year, a corporation is required to compute its tax liability under both systems and pay whichever is greater. Each tax system has its own rules for the measurement of income and use of deductions, and the tax rates for each differ.

In general, the corporate AMT is erected upon a broader definition of income and a less generous set of deductions. Furthermore, most business tax credits, such as the research tax credit, cannot be used to reduce AMT liability. In computing its AMT, a corporation begins with its regular taxable income and modifies it through a series of additional computations known as adjustments and preferences. Adjustments may or may not raise taxable income for the AMT, while preferences are determined on a property-by-property basis and affect taxable income only to the extent that they increase it.³²

Because the corporate AMT is based on a broader measure of taxable income than the regular corporate income tax, nearly every corporation would pay the AMT every year if it were not the case that the AMT rate is much lower than the maximum rate under the regular tax system. The tax rate under the corporate AMT is 20%, whereas the top corporate tax rate is 35%. This means that a corporation's taxable income must be at least 75% greater under the AMT than the regular tax before the corporation must pay the AMT. A firm ends up paying the AMT mostly because of differences in the timing of certain deductions, especially the deduction for depreciation.

Many corporations can and do switch between paying the AMT and paying the regular tax. As a result, a credit for taxes paid under the AMT is allowed to keep the AMT from leading to the collection of taxes in excess of the value of timing differences for certain deductions. The tax credit for AMT payments can be used only to offset future regular income tax liability; any unused credits may be carried forward indefinitely. But the AMT credit cannot be used to lower a business taxpayer's regular tax liability below its tentative minimum tax. This means that if a

³¹ Since 1998, so-called small corporations have been exempt from the AMT. To qualify for the exemption, a corporation's average gross receipts cannot exceed \$7.5 million in the three previous tax years.

³² Andrew Lyon, "Alternative Minimum Tax, Corporate," in *The Encyclopedia of Taxation & Tax Policy*, Joseph J. Cordes, Robert D. Ebel, and Jane G. Gravelle, eds. (Washington: Urban Institute Press, 2005), p. 9.

corporation pays the AMT in two consecutive years and then uses its AMT credits over the following two years, its total tax liability in that period would be equal to what it would have been if it had paid the regular tax only. In effect, the AMT accelerates payment of the regular tax. There is an opportunity cost to this acceleration in the form of forgone earnings from using the AMT payments for some other purpose.³³ The longer the gap between paying the AMT and using all AMT credits, the greater this cost.

As shown in **Table 2**, the AMT credits claimed by drug firms varied widely from year to year. Nevertheless, on the whole, they accounted for a small share of the credits used in any given year. In 2005, for example, the AMT credits used by pharmaceutical firms came to 2% of the AMT credits claimed by all industries.

Such an outcome is not surprising. The corporations that are most likely to pay the AMT are those that invest heavily in assets subject to accelerated depreciation under the regular tax system, relative to their earnings. Differences in the treatment of depreciation of these assets between the corporate AMT and the regular tax system account for most of the adjustments and preferences that enter into the computation of the AMT. On the whole, drug firms invest less in such assets as a share of earnings than the manufacturing sector as a whole, which typically accounts for half of total corporate AMT liability in a tax year. In 2002, for instance, pharmaceutical firms spent the equivalent of 5.0% of their value added on plant and equipment; by contrast, manufacturing firms spent 6.6% of their combined value added for the same purpose.³⁴

General Business Credit

The general business credit (GBC) under IRC Section 38 consists of 31 separate and distinct tax credits.³⁵ Each credit is computed separately on the appropriate tax form. In general, the GBC may not exceed a business taxpayer's net regular income tax, less the greater of its tentative minimum tax liability, or 25% of the net regular tax liability above \$25,000. In this case, a taxpayer's net regular income tax liability is defined as the sum of its regular tax liability and alternative minimum tax liability, less all non-refundable credits. If the GBC is greater than this limitation in a tax year, the excess may be carried back one year or forward up to 20 years (with some exceptions). Thus, the GBC a firm may claim in a tax year is the sum of GBCs carried forward to that year, the GBC for that year, and GBCs carried back to that year.

As **Table 2** shows, most of the drug industry's allowable claims for the GBC since 1990 apparently have been derived from a single credit: the credit for increasing research expenditures

³³ Ibid., p. 10.

³⁴ The source for the data is the 2002 economic census conducted by the U.S. Bureau of the Census. The census is conducted every five years; data from the 2007 census are still being collected. See <http://www.census.gov/econ/census02>.

³⁵ The GBC in any tax year is the sum of the investment credit, the work opportunity credit, the alcohol fuels credit, the research credit, the low-income housing credit, the enhanced oil recovery credit, the disabled access credit, the renewable electricity production credit, the empowerment zone employment credit, the Indian employment credit, the employer social security tip credit, the orphan drug credit, the new markets credit, the small employer credit for pension plan startup costs, the credit for employer-provided child care facilities and services, the qualified railroad track maintenance credit, the biodiesel and renewable diesel fuels credit, the low-sulfur diesel fuel production credit, the marginal oil and gas well production credit, the distilled spirits credit, the advanced nuclear power facility production credit, the non-conventional fuels credit, the energy-efficient home credit, the energy-efficient appliance credit, the alternative motor vehicle credit, the alternative fuel vehicle refueling property credit, the Hurricane Katrina housing credit, the Hurricane Katrina, Rita, and Wilma employee retention credit, the mine rescue team training credit, the credit for contributions to selected community development corporations, and general credits for an electing large partnership.

under IRC Section 41. From 1991 to 2006, the research credit claimed by the industry exceeded its allowable GBC in every year except 1995, 2003, and 2005. In the same period, the cumulative value of the research credit claimed by the industry exceeded the cumulative value of its allowable GBC by \$1.1 billion. These differences indicate that at least some pharmaceutical firms have had sizable reserves of unused research tax credits to draw upon to reduce their regular tax liabilities in future years.

Research Tax Credit

Under IRC Section 41, business taxpayers may claim a tax credit for their spending on qualified research above a base amount.³⁶ The incremental design is intended to give firms an incentive to spend more on research than they otherwise would. The credit lowers the after-tax cost of undertaking qualified research above the base amount: one dollar of the credit reduces that cost by the same amount.

The research credit is composed of five separate and distinct non-refundable credits: a regular research credit, an alternative incremental research credit (or AIRC), an alternative simplified incremental credit (or ASIC), a credit for contract basic research, and a credit for contract energy research. All five are due to expire at the end of 2009, and the AIRC is unavailable in 2009. A business taxpayer may claim no more than the basic and energy research credits and one of the remaining three in a single tax year. To prevent a taxpayer from reaping a double tax benefit from the same expenditure, any research tax credit claimed must be subtracted from the amount of qualified research expenses deducted under IRC Section 174.

Most claims for the credit involve the regular credit. It has been extended 13 times and significantly modified six times. The credit is equal to 20% of a firm's qualified spending on eligible research conducted in the United States and its territorial possessions above a base amount. Several rules governing the use of the credit tend to push its marginal effective rate below its statutory rate for many of the firms that use it. Of particular importance are the definition of qualified research and the requirements that the deduction for qualified research expenses under IRC Section 174 be reduced by the amount of the research tax credit, and that the base amount equal 50% or more of current-year research expenses. The regular, alternative, and basic research credits apply to the following expenses only: wages and salaries of researchers, supplies and materials used in qualified research, leased computer time for qualified research, and 65% to 100% of payments for contract research (depending on the nature of the research and the type of entity conducting it).

Among all industries, the drug industry is a leading beneficiary of the research credit: in 2006, it claimed \$902 million in research tax credits, or 12% of the total amount of such claims by all industries.

Yet there is reason to suspect that the credit has not had a major impact on investment in new drug development in recent years. From 2000 to 2006, the drug industry's total claims for the credit represented 3% of total domestic R&D spending by PhRMA member companies. In addition, even drug firms that spend hundreds of millions of dollars or more on R&D cannot expect to take advantage of the regular credit in a given tax year. A 2001 CRS report estimated that Merck was unable to claim a regular research tax credit in 1998, despite spending \$1.8 billion

³⁶ For more details on the design of the credit and initiatives in the 110th Congress to modify it, see CRS Report RL31181, *Research and Experimentation Tax Credit: Current Status and Selected Issues for Congress*, by Gary Guenther.

on R&D that year.³⁷ The explanation for this result lay in the rules governing the regular credit's use, especially the requirement that the base amount be equal to 50% or more of current-year expenditures on qualified research. These rules may also explain why relatively few drug firms claim the research credit from year to year: in 2005, for instance, no more than one in five of pharmaceutical firms that filed a corporate income tax return claimed the research tax credit.

Orphan Drug Credit

Only one of the credits shown in **Table 2** seems targeted at the drug industry: the orphan drug tax credit. In 2006, firms classified in the industry by the IRS contributed 52% of the total value of claims for the credit by all industries.

Under IRC Section 45C, a firm may claim a tax credit equal to half the cost of human clinical trials for drugs intended to treat rare diseases; such drugs are also known as orphan drugs. The credit indirectly subsidizes the cost of capital for investment in the development of such drugs, as human clinical trials, which are conducted in three phases, constitute the most time-consuming and costliest step in the new drug development process.³⁸ The statutory provision defines a rare disease or condition as one likely to afflict fewer than 200,000 individuals residing in the United States, or one likely to afflict more than 200,000 such individuals but for which there is no realistic prospect of recovering R&D costs from U.S. sales alone. The credit applies to expenditures for the supplies and the wages and salaries of researchers used in clinical trials for orphan drugs, but not for the structures and equipment used in the trials. It is a permanent provision of the tax code and a component of the general business credit, and thus subject to its limitations.

Since the orphan drug credit was enacted in 1983 as one of a series of measures aimed at stimulating increased investment in the development of new drugs to treat rare diseases and conditions, at least 325 such drugs have gained regulatory approval in the United States.³⁹ But contrary to the credit's intended purpose, some of them went on to become major sources of revenue for their producers, including Glaxo Wellcome's anti-AIDS drug Retrovir AZT, Amgen's anti-anemia drug Epogen, and Genentech's human growth hormone Protropin.⁴⁰

Federal Tax Burden on the Drug Industry and Major U.S. Industries from 2000 to 2006

Generally, the federal tax burden on an industry refers to how the tax code affects its return on past investment. This effect emerges through the definition of taxable income, adjustments to taxable income (e.g., deductions and exemptions), tax rates, and adjustments to tax liability (e.g., tax credits and minimum tax payments). For the most part, these provisions serve the dual purpose of raising the revenue needed to fund government operations and programs and offering firms meaningful incentives to engage in or eschew certain activities. The tax credit for increasing research expenditures obviously exemplifies the second purpose. Expressed in its simplest terms, an industry's federal tax burden indicates how much of its profits it must surrender to comply

³⁷ CRS Report RL30479, *The Research and Experimentation Tax Credit: Current Law and Selected Policy Issues for the 106th Congress*, by Gary Guenther.

³⁸ Pharmaceutical Research and Manufacturers of America, *2002 Industry Profile*, pp. 19-22.

³⁹ As of May 16, 2008.

⁴⁰ Standard & Poor's, *Healthcare: Pharmaceuticals*, p. 21.

with current tax law. As this burden expands and all other things being equal, firms have fewer funds than they otherwise would to use as they wish.

Economists define a firm's tax burden as its share of real pre-tax economic income paid in taxes. But it is difficult to determine a firm's economic income from business tax return data, as certain provisions in the tax code drive a wedge between a business taxpayer's economic income and its taxable income. So another approach must be taken to measure business tax burdens. One option is to substitute taxable income as determined under current federal tax law for pre-tax economic income. This approach is used here.

A widely used measure of an industry's federal tax burden is its average effective tax rate, which is the ratio of its federal income tax liability after credits to its taxable income, expressed as a percentage. As such, the ratio reveals the net effect of the federal tax code on the industry's pre-tax returns on previous investments. Some economists construe this effect as the extent to which the tax code penalizes or rewards the economic activities of the firms making up the industry.

There are some limitations to the usefulness of the average effective tax rate as a measure of an industry's federal tax burden. One limitation is that the rate reflects the impact of the tax code on the returns to an industry's previous investments; thus it may be an unreliable indicator of the federal tax burden on current or future investments. In addition, average effective tax rates do not provide a comprehensive measure of the federal tax burden for an industry because they cannot capture the influence of provisions in the tax code that accelerate the timing of tax deductions or delay the recognition of income for tax purposes. A better measure would be the marginal effective tax rate for an industry, which would capture the effect of all relevant tax provisions on its pre-tax returns on new investment.⁴¹ But it is difficult to compute such a rate for most industries because the value of some widely used tax benefits (e.g., expensing of R&D costs) cannot be estimated using available financial or tax return data, and not all firms in an industry invest the same amount in the same mix of assets in a given tax year. Nonetheless, if average effective tax rates are applied consistently across industries and over time, they can shed light whether their federal tax burdens differ, and if so, to what extent.

Table 3 shows the average effective federal tax rates for the drug industry and all major U.S. industries from 2001 to 2006. As noted above, the rates compare the industries' federal income tax liability after all credits except the foreign tax credit with their worldwide taxable income (as reported on their federal income tax returns). As such, they address neither the domestic tax burden on domestic income nor the worldwide tax burden on worldwide income for the industries. Instead, the rates represent something of a hybrid of the two measures: the federal tax burden on domestic income plus foreign income that has been recognized for federal tax purposes. As noted earlier, the foreign tax credit should be excluded from an industry's net tax liability because the credit is intended to prevent the double taxation of foreign-source income. Including it would understate the federal tax burden on the industries, in some cases by a significant margin.

⁴¹ The marginal effective tax rate on business income is the expected pre-tax rate of return minus the expected after-tax rate of return on a new investment, divided by the pre-tax rate of return. It typically accounts for the statutory tax rate, accelerated depreciation allowances, and economic rates of depreciation adjusted for inflation. Nonetheless, the rate can be adjusted to reflect the influence of other detailed provisions of the tax code. In essence, the rate summarizes the tax incentives to invest in a particular asset or set of assets. As such, it may bear little relation to an industry's average effective tax rate, which measures the actual tax paid in a given year as a share of actual capital income in that year earned from all past investment. For more information on the computation and uses of the marginal effective tax rate, see Don Fullerton, "Marginal Effective Tax Rate," in *The Encyclopedia of Taxation and Tax Policy*, Joseph J. Cordes, Robert D. Ebel, and Jane G. Gravelle, eds. (Washington: Urban Institute Press, 1999), pp. 231-233.

The data in the table indicate that the drug industry's federal tax burden in 2001 to 2006 was similar to the average tax burden for all industries. Such a finding may come as a surprise to those who have the impression that the industry long has benefitted unfairly or disproportionately from certain business tax preferences. Though the table does not show this, the industry's tax burden did rise in the late 1990s, driven by a phase-out of the possessions tax credit that began in 1997 and lasted through 2005.

Table 3. Average Effective Tax Rates for the Drug Industry and Major U.S. Industries from 2001 to 2006 (%)

Industry	2001	2002	2003	2004	2005	2006	Average Rates for 2001 to 2006
All Industries	33.0	33.0	32.5	33.0	33.0	33.0	33.0
Agriculture, Forestry, Fishing, and Hunting	28.0	27.0	29.0	30.0	30.0	29.0	29.0
Mining	33.0	34.0	33.0	35.0	35.0	33.0	34.0
Construction	31.0	32.0	32.0	32.0	33.0	32.0	32.0
Manufacturing	32.0	33.0	32.0	33.0	33.0	33.0	33.0
Drugs	32.0	31.0	30.0	31.0	32.5	32.5	31.5
Transportation, Warehousing & Utilities	32.0	31.0	29.0	32.0	31.0	31.5	31.0
Wholesale & Retail Trade	33.0	33.0	33.0	33.0	33.0	33.5	33.0
Finance, Insurance & Real Estate	34.0	33.0	33.5	33.0	33.0	34.0	33.5
Information	31.5	30.0	32.0	33.0	34.0	35.0	32.0
Services	32.0	33.0	32.0	33.0	33.0	32.0	32.5

Source: Calculations done by CRS using data from U.S. Internal Revenue Service, Statistics of Income Division, *Corporation Source Book*, 2001 to 2006; covers tax returns only, with and without net income; available at <http://www.irs.ustreas.gov/tatstats>.

Note: As calculated here, the average effective tax rate for an industry is the ratio of its federal income tax liability after all credits, **except the foreign tax credit**, to its worldwide taxable income, expressed as a percentage.

If marginal effective federal tax rates could be computed for typical investments made by the industries shown in **Table 3**, it is likely that the rate for the drug industry would be among the lower ones. This is because the effects of some tax preferences that tend to benefit drug firms more than other firms are not fully reflected in average effective tax rates. These preferences involve both the deferral of federal income taxes and accelerated depreciation. Three tax preferences in particular are likely to yield significant tax savings for U.S.-based drug firms and thus warrant further examination: (1) the deferral of federal income taxes on net income retained by foreign subsidiaries of U.S.-based corporations; (2) the expensing (or deduction as a current cost) of qualified research spending; and (3) the expensing of advertising and promotional costs.

Deferral of Federal Income Taxes on Foreign-Source Income

As noted above, the federal government taxes corporations based or chartered in the United States on their worldwide income and grants them tax credits for foreign income tax payments they make on foreign-source profits up to their federal tax liability on those profits. But federal tax law does not treat all foreign-source income equally. Profits earned by foreign branches of a U.S.-based corporation are subject to federal taxation in the year when they are earned, regardless of

whether the profits are repatriated to the U.S. corporate parent. In contrast, profits earned by foreign corporate subsidiaries of the same corporation are subject to U.S. taxation only when they are repatriated to the parent firm in the form of dividends, royalty payments, or other income. The subsidiaries' profits may be taxed by the host countries, but any profits they retain are exempt from federal taxation until the profits are repatriated. Such an exemption represents a deferral of U.S. income tax liability.

Deferral of this variety can generate a substantial tax benefit, particularly in cases where U.S. firms locate subsidiaries in countries with lower tax rates than the United States. The reason lies in the time value of money. In essence, a dollar received today is worth more than the same dollar received in some future year. So the longer a taxpayer can defer a tax payment, the less it is worth in current dollars.⁴² As a result, U.S.-based firms with subsidiaries in countries with lower tax rates than the United States can reduce the present value of their federal tax burden by having the subsidiaries retain their earnings for one or more years. Although these subsidiaries may pay income taxes on their annual earnings to host-country governments, those taxes would be lower than the U.S. income taxes that would be due on the same profits in the year when they were earned. Thus, the opportunity to defer federal taxes on foreign-source income gives U.S.-based firms a significant incentive to invest in countries with lower income tax rates than the United States.⁴³

There is some evidence that U.S.-based drug firms have taken advantage of this opportunity. According to a 2004 article in *Tax Notes*, the effective foreign income tax rate on the foreign profits of six major U.S. pharmaceutical firms was 17.6% in 2003, while the maximum U.S. corporate tax rate was 35%.⁴⁴ Unrepatriated foreign earnings reported by the same six companies rose from \$10.1 billion at the end of 1993 to \$101.0 billion at the end of 2004, a tenfold increase.⁴⁵ And another report in *Tax Notes* pointed out that six pharmaceutical firms were among the top 20 of 67 U.S.-based multinational firms ranked according to accumulated undistributed or unrepatriated foreign earnings reported in the 10-K reports they filed for 2003 with the Securities and Exchange Commission.⁴⁶

Temporary Dividends Received Deduction Under IRC Section 965

Further evidence that the drug industry is a major beneficiary of the opportunity to defer federal taxes on profits earned by the foreign corporate subsidiaries of U.S.-based corporations comes from the industry's response to a provision in the American Jobs Creation Act of 2004 (AJCA,

⁴² To some analysts, the deferral of tax payments is analogous to receiving an interest-free loan from the federal government. For more details on the benefits of tax deferral, see Emil M. Sunley, "Deferral of Tax," in *The Encyclopedia of Taxation and Tax Policy*, Joseph J. Cordes, Robert D. Ebel, and Jane G. Gravelle, eds. (Washington: Urban Institute Press, 2005), pp. 75-77.

⁴³ U.S. Congress, Senate Committee on the Budget, *Tax Expenditures: A Compendium of Background Material on Individual Provisions*, committee print, 106th Cong., 2d sess. (Washington: GPO, Dec. 2000), p. 32.

⁴⁴ The six firms are Pfizer, Johnson & Johnson, Merck, Bristol-Myers Squibb, Abbott Laboratories, and Schering Plough. See John A. Almond and Martin A. Sullivan, "Drug Firms Park Increasing Share of Profits in Low-Tax Countries," *Tax Notes*, Sept. 20, 2004, p. 1,337.

⁴⁵ Martin A. Sullivan, "U.S. Drug Firms Bring Home \$98 Billion," *Tax Notes*, Apr. 17, 2006, p. 285.

⁴⁶ The analysis focused on the top 100 of the Fortune 500 in 2003. Of these companies, 67 reported unrepatriated foreign profits of \$352.5 billion in 2003. Six of the top 20 companies were pharmaceutical firms: Pfizer, Merck, Bristol-Myers Squibb, Schering-Plough, Eli Lilly, and Wyeth. They reported a total of \$95.6 billion in accumulated unrepatriated foreign profits in 2003, or 27% of the total for the entire sample of 67 companies. See John A. Almond and Martin A. Sullivan, "While Congress Dawdles, Trapped Foreign Profits Surge," *Tax Notes*, June 28, 2004, pp. 1587-1592.

P.L. 108-357) that granted U.S.-based firms a temporary tax reduction for the repatriation of some of those profits.

Under IRC Section 965, which was added by AJCA, U.S. corporations could claim a deduction equal to 85% of the cash dividends above a base-period-amount they received from their controlled foreign corporations (CFCs) and then invested in the United States according to an eligible plan approved by a top corporate officer and the board of directors.⁴⁷ For corporations paying a marginal tax rate of 35%, the deduction lowered the tax rate on any dividends received to 5.25%: 0.35×0.15 . Corporations were allowed to claim the dividends received deduction (DRD) once: either in their last tax year before October 22, 2004 (the date when AJCA was signed into law) or their first tax year during the 12 months starting on October 22, 2004. The base-period amount for a corporation was defined as the average amount of cash dividends it received from CFCs in three of the five most recent tax years ending on or before June 30, 2003, disregarding the years with the lowest and highest repatriation amounts. In addition, the DRD was limited to the greater of \$500 million, or the amount of earnings permanently reinvested outside the United States (as shown on a firm's most recent balance sheet after June 30, 2003), or 35% of the tax liability attributed to earnings permanently reinvested outside the United States.

A recent study by the Internal Revenue Service (IRS) found that 843 U.S.-based corporations claimed the one-time DRD by repatriating \$362 billion in cash dividends from 2004 through 2006.⁴⁸ Drug firms accounted for 3% of all the firms claiming the deduction but contributed 32% of the entire amount of repatriated cash dividends. The average drug firm repatriated \$3.6 billion in qualifying dividends, compared to \$370 million for the average firm. In addition, drug firms claiming the deduction reported permanently reinvested foreign earnings equal to 13% of their assets; for all firms claiming the deduction, the same ratio was under 2% of their assets.

Transfer of Intangible Assets Like Drug Patents to Low-Tax Countries

The opportunity to defer U.S. taxes on the profits of foreign corporate subsidiaries is linked to a practice used by major U.S.-based pharmaceutical firms to reduce their worldwide tax burdens. It entails the transfer of drug manufacturing and intangible assets like drug patents to offshore subsidiaries in countries whose corporate tax rates are lower than those of the United States.

While the extent of this practice and its impact on the federal tax burdens of drug firms are not well-documented, its basic elements are well-established.⁴⁹ In what could be regarded as the standard or classic case, seeking to lower the effective worldwide tax rate it reports to shareholders, a U.S.-based drug company transfers a patent for a drug it has developed to a subsidiary located in a country with lower corporate tax rates than the United States. The subsidiary then helps fund further research in the United States on the drug, allowing it to claim ownership of the patent without having to buy it from its American parent.⁵⁰ Once the drug is approved for sale in the United States, the subsidiary produces it at a cost of a few cents a pill. The pills are then shipped to the American parent, which sells them to pharmacies or wholesalers for several dollars a pill. But in accounting for the profit from U.S. sales of the drug on its federal income tax return, the American parent company attributes almost the entire amount to the

⁴⁷ A controlled foreign corporation is a corporation located in a country outside the United States in which U.S. shareholders own directly or indirectly more than 50% of either the foreign corporation's total combined voting power or the total value of all stock on any day of a tax year.

⁴⁸ Melissa Redmiles, "The One-Time Received Dividend Deduction," *Statistics of Income Bulletin*, Spring 2008 (Washington: Internal Revenue Service, 2008), p. 104.

⁴⁹ See Alex Berenson, "Drug Makers Reap Benefits of Tax Break," *New York Times*, May 8, 2005, p. 20.

⁵⁰ Alex Berenson, "Tax Break Used by Drug Makers Failed to Add Jobs," *New York Times*, July 24, 2007, p. C1.

foreign subsidiary, not itself, because the subsidiary holds the patent for the drug. The final result is that most of the profit is transferred to the host country for the subsidiary and taxed there, while the remainder is taxed at a higher rate in the United States. No federal income tax can be levied on the subsidiary's share of the profit until it is repatriated.

This practice is not necessarily illegal under U.S. tax law. But it does make it possible to use loopholes or gaps in the law to shelter profits in so-called foreign tax havens. Since drug prices are higher in the United States than in most other developed countries, the legality of this practice has been questioned. Some argue such a price difference is proof that the vast share of industry profits should be attributed to U.S. operations, not to any foreign operations. Yet that apparently is not the case. According to a 2006 analysis by Martin Sullivan of Tax Analysts, nine of the largest U.S. pharmaceutical firms reported to shareholders that foreign earnings accounted for 69.9% of their combined worldwide profits in 2005, up from 39.2% in 1999.⁵¹ Proceeding on the assumption that an industry's profits should be assigned to the location of "value-creating economic activity" for tax purposes, Sullivan estimated that reported foreign profits should have accounted for 43% of the combined worldwide profits for these firms in 2005. This meant that an additional 27% of the firms' worldwide profits that year should have been subject to U.S. taxation.⁵²

Expensing of Qualified Research Spending

Drug firms also derive substantial benefit from the tax treatment of research expenditures under IRC Section 174. Under that provision, a business taxpayer may deduct as a current expense (or expense) its research expenditures in the tax year when they are made.⁵³ To qualify for this treatment, those expenditures must meet the following criteria: (1) they must relate to a firm's trade or business, (2) they cannot be considered capital costs, and (3) they must be directed at "activities intended to discover information that would eliminate uncertainty concerning the development or improvement of a product."⁵⁴ In practice, only the wages and salaries of research personnel, the cost of supplies and materials used in qualified research, and related overhead costs may be deducted under IRC Section 174. By contrast, the cost of structures and equipment used in this research must be recovered over 15 years and three years, respectively, using allowable depreciation methods.

Business spending on R&D typically creates intangible assets (such as patents) that generate a stream of revenue over a number of years. Such an outcome indicates that the economic life of these assets is longer than one year, a view that has been backed by several studies.⁵⁵ So it seems reasonable and fair that a firm, in computing its taxable income, should treat its spending on R&D

⁵¹ Martin A. Sullivan, "Drug Firms Move Profits to Save Billions," *Tax Notes*, Aug. 7, 2006, p. 472.

⁵² *Ibid.*, p. 472.

⁵³ Under IRC Section 174(b), business taxpayers have the option of treating R&D expenditures as a deferred expense and amortize them over a period of not less than 60 months, beginning with the month a taxpayer first realizes benefits from the expenditures.

⁵⁴ See Internal Revenue Service Final Regulation §1.174-2(a)(1).

⁵⁵ Estimates of the rate of depreciation for R&D capital range from 15% to 30% per year. See James R. Hines, Jr., "No Place Like Home: Tax Incentives and the Location of R&D by American Multinationals," NBER Working Paper 4574 (Cambridge, MA: National Bureau of Economic Research, Dec. 1993), p. 7; and Bronwyn H. Hall and John van Reenen, "How Effective Are Fiscal Incentives for R&D? A Review of the Evidence," NBER Working Paper 7098 (Cambridge, MA: National Bureau of Economic Research, April 1999), p. 6.

as a capital expense that is recovered over the useful life of the assets it generates, using an appropriate depreciation method.

Yet the tax code allows firms to treat R&D expenditures as a current expense rather than a capital expense. This option gives rise to a significant subsidy for business R&D investment in the form of a reduced marginal effective tax rate on the returns to this investment. In theory, expensing (or the deduction of the entire amount of a capital expenditure in the year when it is made) lowers the marginal effective tax rate on the returns to investment in affected assets to zero.⁵⁶ The addition of the research tax credit under IRC Section 41 makes the rate negative for eligible investments. Consequently, the user cost of capital for R&D investment is significantly lower than for many other investments a firm might make, including the acquisition of new plant and equipment.⁵⁷ Supporters of the expensing of R&D expenditures say that such a subsidy is justified on the grounds that it addresses a market failure associated with investment in research: namely, that firms tend to invest less than optimal amounts in research because they cannot appropriate all the returns to innovation.

Drug firms are likely to benefit from this tax subsidy more than many other firms because of the drug industry's strong propensity to invest in R&D. In 2006, according to estimates by the National Science Foundation (NSF), drug firms spent an estimated 13.5% of their domestic net sales on R&D performed in the United States. By contrast, the same ratio for all industries was 3.4%; for manufacturing firms, 3.6%; and for non-manufacturing firms, 2.9%.⁵⁸

Drug firms spent \$38.8 billion on R&D in 2006, according to the NSF. Assuming that its average effective federal tax rate that year was the same as its average effective federal tax rate for 2000 to 2005 (31%), and that the entire amount could be deducted as a current expense under IRC Section 174, the industry was able to lower its tax liability in 2006 by \$12 billion by deducting the full amount of its R&D expenditures.⁵⁹

Expensing of Advertising Spending

Drug firms also appear to benefit disproportionately from the tax treatment of outlays for business advertising. Under current federal tax law, advertising expenses are deductible in the tax year when they are incurred, provided they pass two tests: (1) they are reasonable in amount; and (2)

⁵⁶ Because of the availability of a research tax credit, the marginal effective rate on a portion of business R&D investment is actually negative.

⁵⁷ This assumes that a firm is unable to benefit from the small business expensing allowance under IRC Section 179. In 2008, a business taxpayer may write off or expense up to \$250,000 of the qualified assets it places in service that year. This allowance is subject to two limitations: a dollar limitation and an income limitation. Under the former, the allowance is reduced by the amount by which total spending on qualified assets in a tax year exceeds a phaseout threshold; in 2008, that threshold is \$800,000. Under the latter, the allowance a taxpayer claims cannot exceed the taxable income it earns through the active conduct of the trade or business in which the qualified assets are used. For more information on the small business expensing allowance, see CRS Report RL31852, *Small Business Expensing Allowance: Current Status, Legislative Proposals, and Economic Effects*, by Gary Guenther.

⁵⁸ National Science Foundation, Division of Science Resources Statistics, *U.S. Business R&D Expenditures Increase in 2006; Companies' Own and Federal Contributions Rise*, InfoBrief, NSF 08-313 (Arlington, VA: Aug. 2008), tables 2 and 3. NSF restricts its measure of R&D expenditures to compensation for researchers and the cost of materials, supplies, and overhead used in R&D.

⁵⁹ It should be noted that the nominal value of this tax savings might be the same even if pharmaceutical firms were required to recover the R&D expenses according to a depreciation schedule based on the economic lives of the intangible assets (mainly patents) they create. But the savings would be spread out over a number of years, reducing its present value in 2006 dollars.

they are related to a firm's lines of business. These expenses must serve the purpose of developing goodwill among customers or soliciting immediate sales.

There is a clear similarity in the tax treatment of outlays for advertising and outlays for R&D: both are deductible as a current expense. Expensing constitutes a significant tax subsidy in that it theoretically leads to a marginal effective tax rate of zero on any profits generated by an asset.

In the case of advertising, this tax treatment would be justified on economic grounds if advertising yielded no benefits for a firm beyond the year when the cost of the advertising is incurred. But this might not be the case. There is some evidence that spending on advertising can create intangible assets with economic lives extending beyond a single year.

In certain markets (including prescription drugs), advertising fosters the growth of what might be called brand recognition and consumer loyalty. These effects can operate like an intangible asset in that they can boost a firm's profits and keep them at levels they might not attain otherwise. For instance, Ernst R. Berndt and three colleagues found in a study of the U.S. market for anti-ulcer drugs that efforts by leading manufacturers to promote H₂-antagonist prescription drugs to physicians through detailing and medical journal advertising had "substantial effects" on the growth of domestic demand for the drugs and the sellers' market shares from 1977 to 1993.⁶⁰ In doing the study, they divided these marketing efforts into those aimed at expanding overall demand for H₂-antagonist drugs, and those aimed solely at expanding the market shares of the leading sellers. Berndt and his colleagues then estimated that the cumulative value of the marketing intended to expand overall demand depreciated at a rate of zero, but that the cumulative value of the marketing intended to expand market shares depreciated at an annual rate of close to 40%.⁶¹ Others have estimated that the depreciation rate for the intangible assets created by commercial advertising falls in the range of 20% to 30%.⁶²

To the extent that advertising creates intangible assets with economic lives of longer than one year, the expensing permitted under current tax law has the effect of lowering the cost of capital for investment in advertising, relative to the cost of capital for investment in assets with longer tax lives, all other things being equal. Still, there is lingering uncertainty about the actual rate at which advertising loses its economic value. Available evidence points to differing conclusions about the economic life of advertising; it also indicates that the true depreciation rate may differ considerably by mode of advertising (e.g., television advertising, magazine advertising, radio advertising).⁶³ As a result, it is difficult to assess to what extent the tax code subsidizes investment in advertising.

Whatever the actual degree of subsidy, there is little question that drug firms benefit more from the expensing of advertising expenditures than many other firms because of their relatively strong propensity to invest in advertising. In 2005, the most recent year for which U.S. corporate tax data are available, the drug industry claimed a total deduction for advertising equal to 4.6% of

⁶⁰ Ernst R. Berndt, Linda Bui, David Reiley, and Glen Urban, "The Roles of Marketing, Product Quality and Price Competition in the Growth and Composition of the U.S. Anti-Ulcer Drug Industry," Working Paper 4904 (Cambridge, MA: National Bureau of Economic Research, Oct. 1994), pp. 35. Detailing is the widespread industry practice of promoting drugs directly to physicians by sending marketing representatives to doctor offices and hospitals.

⁶¹ *Ibid.*, p. 36.

⁶² See Mark Hirschey, "Intangible Capital Aspects of Advertising and R&D Expenditures," *Journal of Industrial Economics*, vol. 30, no. 4, June 1982, pp. 375-389.

⁶³ U.S. Congressional Budget Office, *Reducing the Deficit: Spending and Revenue Options* (Washington: GPO, 1997), p. 377.

business receipts; for all industries, the share was 1.2%.⁶⁴ Drug firms deducted \$13.1 billion for advertising that year, yielding a tax savings of \$4.3 billion at the industry's average effective federal tax rate of 32.5% that year.

Federal Tax Policy and Investment in New Drug Development

Tax policy is one of many channels through which the federal government influences the domestic climate for new drug development. Business taxation helps shape this climate through its impact on a firm's user cost of capital for R&D investment and its supply of internal funds (or retained earnings).

The user cost of capital is the cost a firm incurs as a result of owning a tangible or intangible asset. It embraces both the opportunity cost of forgoing other investments and the direct costs of ownership, such as depreciation, the acquisition cost of the asset, and taxes. In general, the user cost of capital indicates the rate of return an investment project must earn in order to break even. As a firm's user cost of capital declines, the number of investment projects it can profitably undertake increases, all other things being equal. There is considerable evidence that business investment responds to changes in the user cost of capital, although the magnitude and duration of the response over the business cycle are matters of ongoing debate and research among economists.⁶⁵

One factor affecting the user cost of capital is the tax burden on the returns to an investment. Generally, as this burden decreases, so does the cost of capital.⁶⁶ A widely used measure of this burden is the marginal effective tax rate. This rate, which is calculated by subtracting the after-tax rate of return on a new investment from the pre-tax rate of return and dividing by the pretax rate of return, reflects the statutory income tax rate faced by a firm, as modified by any tax provisions that subsidize or penalize the investment.

Under current law, the federal tax burden on the returns to R&D investment is relatively low because of two research tax subsidies discussed earlier: (1) the tax credit for increases in research spending above a base amount under IRC Section 41, and (2) the option to deduct qualified research expenditures as a current expense under IRC Section 174. In combination, they have the potential to push the cost of capital for R&D investments below that of most other investments a firm might make, such as purchases of plant or equipment or instituting a new training program for employees. According to an analysis by economist Bill Cox, the credit and expensing allowance have the combined effect of taxing the returns to R&D investment at a negative rate, which is to say that after-tax rates of return exceed pre-tax rates of return.⁶⁷

The same two tax subsidies can also boost R&D investment by increasing a firm's cash flow or supply of internal funds. Some firms base their annual R&D budgets on the amount of money they expect to have on hand after paying all expenses in a given year. For them, the cost of

⁶⁴ Internal Revenue Service, Statistics of Income Division, *2005 Corporation Source Book*, Publication 1053 (Washington).

⁶⁵ Harvey S. Rosen, *Public Finance*, 6th edition (New York: McGraw-Hill/Irwin, 2002), p. 409.

⁶⁶ For a discussion of the impact of taxes on the user cost of capital, see Jane G. Gravelle, "Cost of Capital," in *The Encyclopedia of Taxation and Tax Policy*, Joseph J. Cordes, Robert D. Ebel, and Jane G. Gravelle, eds. (Washington: Urban Institute Press, 1999), pp. 68-70.

⁶⁷ See CRS Report 98-871, *Science, Engineering, and Mathematics Education: Status and Issues*, by Christine M. Matthews, pp. 14-18.

internal funds may be significantly lower than the cost of external funds, such as capital raised through borrowing or issuing new shares of stock. Small start-up biotechnology firms are especially likely to find themselves in this position, as potential investors or lenders may lack the needed information to evaluate their long-term prospects for commercial success. A firm's supply of internal funds depends in part on how much it earns in profits and how much of those profits it must set aside to cover its anticipated income tax liability. In the short run, firms that rely heavily on retained earnings to finance new R&D investments can invest more as their tax liabilities fall, all other things being equal. Of course, a firm could use any increase in cash flow for other purposes, including hiring new employees, training current employees, or paying higher dividends to shareholders or owners.

In addition, the opportunity under federal tax law to move profits to subsidiaries located in low-tax countries through the transfer of drug patents to those subsidiaries and the deft use of transfer pricing can make it possible for major U.S.-based pharmaceutical firms to reduce their worldwide tax burden.

An indicator of the effect of tax policy on new drug development is the drug industry's federal tax burden, as measured by average effective tax rates. From 2000 to 2006, the industry's rate was nearly the same as the average rate for all industries. Yet in the same period, the average drug firm devoted a much higher percentage of its revenue to R&D than the average firm. So while the average drug firm pays about the same amount of federal income tax per dollar of taxable income as the average firm, the former spends a larger share of each dollar of gross income on the development of new technology. This difference suggests that new drug development is driven by forces other than federal tax subsidies. Among the key ones are the opportunities for novel drug compounds opened up through advances in basic research, the regulatory requirements for the drug approval process, the competitive strategies of drug firms, and the potential earnings from investing in the development of new drugs.⁶⁸

It is also worth noting that not all drug firms are affected equally by federal taxation. The typical pharmaceutical firm has profits and thus can take advantage of the research and orphan drug tax credits, the expensing of advertising and research expenditures, and the deferral of profits earned by foreign subsidiaries to lower its tax burden and boost its after-tax rate of return on equity. By contrast, the typical biotech firm has a net operating loss and thus can take advantage of none of those tax incentives in the short run. The typical generic drug firm has a tax profile that more closely resembles that of the pharmaceutical firm, with the exception that the former spends a fraction of what the latter spends on drug discovery, drug testing and clinical trials, and advertising and promotion.

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⁶⁸ U.S. Government Accountability Office, *New Drug Development: Science, Business, Regulatory, and Intellectual Property Issues Cited as Hampering Drug Development Efforts*, GAO-07-49 (Washington: Nov. 2006), pp. 25-36.

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